K012208

SEP - 7 2001

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## 510(k) Summary

Prepared July 12, 2001

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K012208

**Submitter's Name and Address**

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Primary Contact: Denise Thompson
(952) 368-1202

Alternate Contact: Brent Taber
(952) 368-1323

**Device Name**

Trade Name: Access® Thyroglobulin Antibody for use on the Access® Immunoassay Systems
Common Name: Thyroglobulin Antibody Enzyme Immunoassay
Classification name: Immunochemical, Thyroglobulin Autoantibody

**Predicate Device**

Kalibre-R™ Thyroglobulin Antibody (TgAb) RIA Kit
Kronus / Boise Research Center
Boise, ID 83713

510(k) Number: K894203

**Device Description**

The Access Thyroglobulin Antibody reagents, Thyroglobulin Antibody calibrators, and the Access Immunoassay Analyzer comprise the Access Immunoassay System for the quantitative determination of thyroglobulin antibody in human serum and plasma.

**Intended Use**

The Access Thyroglobulin Antibody (TgAb) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease, nontoxic goiter, and Graves' disease.

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## Comparison of Technological Characteristics

| Parameter | Access AccuTnI | Dimension RxL TROP |
|---|---|---|
| Intended Use | The Access® Thyroglobulin Antibody (TgAb) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access® Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease, nontoxic goiter, and Graves' disease. | The KRONUS Thyroglobulin Antibody kit quantitatively measures human serum autoantibodies to thyroglobulin antigen. Serve as an aid in the diagnosis of certain thyriod disorders, such as Hashimoto's thyroiditis, non-toxic goiter and Graves' Disease. |
| Analyte Measured | Thyroglobulin Antibody | Thyroglobulin Antibody |
| Standarization | NIBSC Anti-Thyroglobulin Serum, Human First International Reference Preparation, WHO Coded 65/93 | NIBSC Anti-Thyroglobulin Serum, Human First International Reference Preparation, WHO Coded 65/93 |
| Technology | Sandwich immunoassay | Sandwich immunoassay |
| Format | **Chemiluminescent** Immunoassay | **Radio**immunoassay |
| Method | Automated | Manual |
| Calibration | Utilizes a stored calibration curve | Requires calibration with every run |
| Sample type | Serum or plasma | Serum only |
| Measuring range | 2.2-2500 IU/ml | 0.3-30 U/ml (3-300 IU/ml) |

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## Summary of Studies

Analytical Specificity: There was no significant interference from potential sample contaminants (total protein, bilirubin, hemoglobin, and triglycerides). Additionally, only one discrepancy between interpretations positive and negative was found between the Access and Kronus thyroglobulin assays for samples form persons with autoimmune disease.

Analytical Sensitivity: The lowest detectable level of thyroglobulin antibody distinguishable from zero (Access Thyroglobulin Calibrator Zero) with 95% confidence was determined to be 1.5 IU/mL. An analytical sensitivity of 2.2 IU/mL will be used in the Access Thyroglobulin Antibody labeling.

Dilution Recovery: Various dilutions of serum samples and serum sample pools were analyzed. The overall mean recovery of the samples was 95% with individual mean sample recoveries varying between 90% and 100%.

Precision: Within run imprecision ranged from 3.99 to 5.04 % CV, between run imprecision ranged from 1.95 to 4.66 % CV, and total imprecision ranged from 4.47 to 6.74 % CV at levels ranging between 34.1 and 1,693 IU/ml.

Hook Effect: The Access Thyroglobulin Antibody assay demonstrated no hook to 350,000 IU/ml.

Relative Sensitivity and Specificity: A total of 296 serum samples (99 with Graves' disease, 97 with Hashimoto's disease, and 100 normals) were used to calculate relative sensitivity and specificity for the Access vs. the Kronus thyroglobulin antibody assays. The study showed good relative sensitivity (79.0%) and relative specificity (87.6%) between the methods.

Method Comparison: A comparison of thyroglobulin antibody values from 276 samples, ranging from approximately <2.2 to 284 IU/ml, were run with both the Access Thyroglobulin Antibody immunoassay and the Kronus Thyroglobulin Antibody immunoradiometric assay. The study demonstrated a correlation coefficient of $r = 0.816$, a slope of $y = 0.957$, and an intercept of -5.886.

Stability: The Access Thyroglobulin Antibody reagents are stable for 56 days after opening. The calibration curve is also stable for 56 days.

## Conclusion

The Access Thyroglobulin Antibody assay, for use on the Access Immunoassay Systems, is substantially equivalent to another test currently in commercial distribution for the measurement of thyroglobulin antibody.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 7 2001

Ms. Denise Thompson
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: K012208
Trade/Device Name: The Access® Thyroglobulin Antibody assay for use on the Access® Immunoassay Systems
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: II
Product Code: DDC
Dated: July 12, 2001
Received: July 16, 2001

Dear Ms. Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.6 INDICATIONS FOR USE STATEMENT



510(k) Number (if known): K012208

Device Name: The Access® Thyroglobulin Antibody assay for use on the Access® Immunoassay Systems.

**Indications For Use:**

The Access Thyroglobulin Antibody (TgAb) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access® Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease, nontoxic goiter, and Graves' disease.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012208

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)